UNITED STATES DISTRICT COURT

DISTRICT OF NEW MEXICO

MOHAMED BASEL ASWAD, M.D., Plaintiff, v. ERIC D. HARGAN, in his official capacity as Acting Secretary of the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	No. 2:16-cv-1367-BRB-SMV

ORDER DENYING PLAINTIFF'S MOTION TO REVERSE OR REMAND ADMINISTRATIVE AGENCY DECISION

Plaintiff Mohamed Basel Aswad, M.D., pleaded guilty to receiving a misbranded drug and delivering such product for pay. In response, the Secretary of the Department of Health and Human Services excluded Plaintiff from participation in federal health care programs, including Medicaid, Medicare, and Tricare, for thirteen years. After appealing this decision within the agency twice to no avail, Plaintiff appeals to this Court. Plaintiff seeks reversal of the agency's decision and a remand directing the exclusion period be reduced to the statutory minimum or, in the alternative, a remand for discovery.[1] This

[1] Plaintiff seeks this relief in a Motion for Summary Judgment. Given the magistrate judge ordered Plaintiff to file a Motion to Reverse or Remand Administrative Agency Decision and the nature of the motion, the Court will construe Plaintiff's Motion

Court has jurisdiction under 42 U.S.C. § 1320a-7(f)(1) and 42 U.S.C. § 405(g). For the reasons stated herein, the Court denies Plaintiff's motion and affirms the Secretary's decision.

I.

The administrative record reveals Plaintiff is the sole oncologist in Deming, New Mexico—a rural, economically depressed town in Luna County—where he has provided oncology, hematology, and internal medicine services to patients in Deming and the surrounding area since 2003. Prior to Plaintiff's exclusion from participation in federal health care programs, sixty percent of his patients were Medicare beneficiaries, thirty-five percent were Medicaid beneficiaries, and five percent were privately insured. As no pharmacy in Deming dispenses oncology medication, Plaintiff must order all oncology medication from pharmacies outside of Deming and receive the medication via mail.

In April 2010, a sales representative from Non-RX called Plaintiff, told Plaintiff it was a large pharmaceutical company that served health care providers across the United States, and attempted to sell to Plaintiff oncology and chemotherapy supplies. In July 2010, Plaintiff started ordering a chemotherapy drug, Bevacizumab, from Non-RX for his patients. This drug was misbranded and not approved by the FDA—a fact of which Plaintiff alleges he was unaware. He paid market price for the drug and it was shipped to him from an Illinois or Tennessee address. Plaintiff received federal health care program reimbursements for administering the drugs to his patients and, making no attempt to hide

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for Summary Judgment as a Motion to Reverse or Remand Administrative Agency Decision.

his purchases of the drug, deposited these reimbursements into bank accounts in his name. Plaintiff purchased the drug from July 2010 to April 2012, when the FDA raided his practice.

Plaintiff argues, upon this raid in April 2012, he learned the drug he purchased from Non-RX was misbranded. While containing the appropriate active ingredient, the drug was not FDA-approved, and its labeling did not bear adequate instructions or the required "Rx only" symbol. The FDA seized used vials of the drug but did not attempt to close Plaintiff's practice. Plaintiff reported his use of a misbranded drug to the New Mexico Medical Board. In November 2014, the board suspended his New Mexico medical license but reinstated it less than three weeks later.

Even though Plaintiff argued he did not know the drug was misbranded, in August 2014, he nonetheless pleaded guilty to receiving a misbranded drug and delivering such product for pay in violation of 21 U.S.C. §§ 331(c) and 333(a)(1), a single strict liability misdemeanor.[2] Plaintiff's plea agreement required him to pay restitution of $1,298,543, the amount he had received from federal health care programs for administering the drug to his patients. The plea agreement further subjected him to a three-year probation period, which was subsequently terminated early in April 2016.

In the meantime, the Secretary of the United States Department of Health and Human Services ("HHS") notified Plaintiff that, because of his criminal conviction, he

[2] 21 U.S.C. § 331(c) prohibits "[t]he receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise." 21 U.S.C. § 333(a)(1) mandates a person who violates § 331 "shall be imprisoned for not more than one year or fined not more than $1,000, or both."

was excluded from participation in federal health care programs for thirteen years. Pursuant to 42 U.S.C. § 1320a-7(c)(3)(B), the New Mexico Human Services Department ("NMHSD") requested a waiver of Plaintiff's exclusion, as he was the sole provider of essential medical services in the Deming area. In February 2016, the Secretary granted the waiver of exclusion regarding oncology and oncology-related services in Luna County. In response to the limited scope of this waiver, the NMHSD requested an amended waiver. The Secretary granted this request, extending the waiver to surrounding counties and to oncology, hematology, and internal medicine services of Medicaid patients and oncology and hematology (but not internal medicine) services of Medicare patients. Plaintiff asserts that while this waiver has significantly alleviated the burden of his exclusion, he remains hampered in his practice of medicine.[3]

In addition to the NMHSD's request of waiver of Plaintiff's exclusion, Plaintiff challenged the Secretary's decision about his exclusion period by appealing the decision to HHS's Departmental Appeals Board ("DAB"), Civil Remedies Division. He argued his exclusion of thirteen years was arbitrary and capricious and requested the production of documents regarding the Secretary's decisions about similarly situated people. In June 2016, an administrative law judge ("ALJ") concluded Plaintiff's thirteen-year exclusion was not unreasonable and denied Plaintiff's request for production of documents. Plaintiff appealed this decision to DAB, Appellate Division, which upheld the ALJ's findings. Plaintiff appealed to this Court.

[3] This waiver is not subject to review. 42 U.S.C. § 1320a-7(c)(3)(B). The Court makes no comment on NMHSD's ability to seek an amended waiver that would also cover internal medicine services of Medicare patients.

II.

This Court reviews decisions to exclude medical service providers from participation in federal health care programs "to determine whether [the Secretary's] factual findings are supported by substantial evidence . . . and whether [the Secretary] applied the correct legal standards."[4] *Sternberg v. Sec'y, Dep't Health & Human Servs.*, 299 F.3d 1201, 1205 (10th Cir. 2002) (quoting *Castellano v. Sec'y of Health & Human Servs.*, 26 F.3d 1027, 1028 (10th Cir. 1994)). Additionally, pursuant to 5 U.S.C. § 706(2), this Court reviews an agency's action under the arbitrary and capricious standard. *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 284 (1974) ("[T]hough an agency's finding may be supported by substantial evidence, . . . it may nonetheless reflect arbitrary and capricious action."); *St. Anthony Hosp. v. U.S. Dep't of Health & Human Servs.*, 309 F.3d 680, 690–91 (10th Cir. 2002) (reviewing HHS's factual findings under the substantial evidence standard and conclusions under the arbitrary and capricious standard). As the parties do not dispute the Secretary's factual findings and Plaintiff does not explicitly challenge whether the Secretary applied the correct legal standard, the question this Court faces is whether the Secretary's decision to increase Plaintiff's exclusion period to thirteen years was arbitrary and capricious.

A final agency decision is arbitrary and capricious if the agency "relied on factors which Congress had not intended it to consider, entirely failed to consider an important

[4] As exclusions from participation in federal health care programs are subject to the same judicial review as decisions regarding social security benefits, *see* 42 U.S.C. § 1320a-7(f)(1), the standard of review derives from 42 U.S.C. § 405(g), the statute governing decisions of the Commissioner of Social Security.

aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579, 1581–82 (10th Cir. 1985) (quoting *Motor Vehicles Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)). Under this narrow standard of review, this Court cannot substitute its own judgment for that of the agency. *Bd. of Cty. Comm'rs v. Isaac*, 18 F.3d 1492, 1496–97 (10th Cir. 1994). With these restraints in mind, the Court now turns to the relevant law.

The Secretary of HHS must exclude "[a]ny individual . . . convicted of a criminal offense related to the delivery of an item or service under subchapter XVIII of this chapter" from participation in federal health care programs. 42 U.S.C. § 1320a-7(a)(1). Unless a waiver of exclusion is granted, the exclusion period cannot be less than five years. 42 C.F.R. § 1001.102(a). Based on certain enumerated aggravating factors, however, the Secretary may increase the exclusion period. *Id.* § 1001.102(b). Two of the aggravating factors, both of which the Secretary found applied to Plaintiff, are that the acts resulting in the conviction (1) caused a financial loss to the government of at least $50,000 (the "Restitution Factor") and (2) occurred over a period of one year or more (the "Duration Factor"). *Id.* Only if the Secretary increases the exclusion period based on aggravating factors may any mitigating factor be considered. *Id.* § 1001.102(c). The Secretary may consider *only* the three enumerated mitigating factors, none of which are relevant to Plaintiff. *Id.*

Plaintiff concedes he is subject to the mandatory exclusion for a minimum of five years based on his conviction, the two aforementioned aggravating factors apply to him, and no mitigating factors apply to him. Plaintiff only challenges the length of his exclusion, claiming that a blanket application of the two aggravating factors without considering the unique and specific circumstances of his case was unreasonable.[5] Specifically, Plaintiff argues the Secretary should have considered his lack of intent in applying the Duration Factor and the high cost of the drug in applying the Restitution Factor. To support this argument, he points to an HHS statement in the Federal Register that aggravating factors are "not intend[ed] . . . to have specific values; rather these factors must be evaluated based on the circumstances of a particular case." 57 Fed. Reg. 3298, 3314 (Jan. 29, 1992).[6] This statement was made in response to a public comment suggesting the regulations give guidance as to how the aggravating and mitigating factors will be weighted. *Id.* HHS declined to give specific values to the factors, explaining such inquiries are highly fact-specific. *Id.*

A statement in the Federal Register explaining why HHS refused to assign specific values to the factors is insufficient to show the Secretary's alleged failure to consider lack of intent or the cost of the drug was arbitrary and capricious. *Nothing* in the regulation

[5] For the sake of argument, this Court will assume Plaintiff's characterization is accurate. It appears, however, the ALJ and DAB Appellate engaged in a more nuanced discussion in upholding the Secretary's decision than Plaintiff suggests. *See* ROA 1–20.

[6] As additional support, Plaintiff also notes the Secretary's consideration of aggravating factors is optional, pursuant to 42 C.F.R. § 1001.102(b). The discretionary nature of the application of aggravating factors has little bearing on whether the application of such factors in this case was reasonable.

requires the Secretary to consider lack of intent in applying the Duration Factor or the cost of a drug in applying the Restitution Factor. HHS could have easily written a regulation requiring such considerations, but it did not. The Secretary complied with its required considerations and determined (1) regardless of Plaintiff's intent, Plaintiff distributed misbranded drugs to patients for over one year and (2) whether the drug cost $100,000 or $1, Plaintiff's actions caused the government to lose almost $1.3 million. Finding these two aggravating factors applied and the mitigating factors did not, the Secretary excluded Plaintiff from federal programs accordingly. Based on this record and the regulation as written, the Secretary's decision simply was not arbitrary and capricious.

Plaintiff also argues that the Secretary must consider Plaintiff's overall trustworthiness when applying either aggravating factor. Plaintiff's support for this argument comes from DAB decisions stating the factors "reflect the degree or level of the provider's untrustworthiness." *See, e.g.*, Robinson, DAB No. 1905, 8 (2004). First of all, although clearly not to the extent Plaintiff would have liked, the ALJ discussed Plaintiff's trustworthiness. *See* ROA 3, 5. Second, as Plaintiff himself notes, trustworthiness is not in itself a factor warranting reduction of an exclusion period. *See* 42 C.F.R. § 1001.102(c); Miranda, DAB No. 2755, 7 (2016). That the factors are designed to *reflect* trustworthiness does not necessitate analyzing the trustworthiness of a person in applying every aggravating and mitigating factor. If HHS intended this sort of trustworthiness analysis, it would have added trustworthiness to the list of enumerated mitigating factors in 42 C.F.R. § 1001.102(c). In the absence of any regulation requiring

the Secretary to consider trustworthiness in applying the factors, this Court cannot say the Secretary's alleged failure to consider Plaintiff's trustworthiness was arbitrary and capricious.[7]

Plaintiff additionally argues the discovery of other cases regarding those similarly situated to Plaintiff should have been allowed. On appeals of exclusions, "[a] party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ." 42 C.F.R. § 1005.7(a). "The ALJ may . . . deny a motion for an order compelling discovery if the ALJ finds that the discovery sought (i) Is irrelevant, (ii) Is unduly costly or burdensome, (iii) Will unduly delay the proceeding, or (iv) Seeks privileged information." *Id.* § 1005.7(e)(2). In Plaintiff's administrative appeal, he requested production of, among other things, all documents related to the Secretary's decisions on whether to exclude individuals convicted of misdemeanor offenses similar to the crime of which Plaintiff was convicted and the length of any such exclusions. ROA 114. The ALJ denied this request, explaining Plaintiff sought privileged documents and cases similar to Plaintiff's were irrelevant. DAB Appellate upheld the denial, reasoning these documents are "clearly irrelevant" and it would be "unduly burdensome" for HHS to locate such documents.

[7] This Court is not unsympathetic to Plaintiff's predicament and commends Plaintiff on his strong arguments concerning "the regulation's lack of symmetry" between the aggravating and mitigating factors and "the Secretary's refusal to consider other circumstances" than those enumerated in the regulation. P. Rep. Br. 9. These arguments, which essentially advocate for a change in the regulation, would properly be made before HHS in a petition for rulemaking. This Court, however, is bound by the regulation as written and a narrow standard of review of the Secretary's decision.

Plaintiff appeals this decision, seeking "production of documents related to the Secretary's decision to exclude and the length of any such exclusion, of individuals convicted of misdemeanor offenses related to the purchase of misbranded drugs from Non-RX." Curiously, Plaintiff does not argue the documents are relevant, material, non-privileged, or not unduly burdensome to retrieve; therefore, those issues are not before this Court. Instead, Plaintiff argues the denial of his discovery request prevents him "from determining whether the length of his exclusion period was imposed on an arbitrary and capricious basis or was reached based on improper criteria such as national origin." Plaintiff cites no authority—and this Court has found none—supporting the notion that this Court can remand for discovery so that Plaintiff can explore his unarticulated suspicion that others similarly situated were treated more favorably. This Court therefore declines to do so.

Plaintiff's Motion to Reverse or Remand Administrative Agency Decision (Docket #23) is DENIED. The Secretary's Decision is AFFIRMED.

CASE CLOSED.

Entered for the Court
this 2d day of February 2018

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Bobby R. Baldock
United States Circuit Judge
Sitting By Designation